

REMARKS

I. *Status Summary*

Claims 1, 2 and 6 are pending in the subject application. Claims 1, 2 and 6 have been examined by the U.S. Patent and Trademark Office (hereinafter "the Patent Office"). Claims 1, 2 and 6 presently stand rejected.

Claims 1, 2 and 6 presently stand rejected under the enablement requirement of 35 U.S.C. §112, first paragraph. The Patent Office asserts that the claims contain subject matter not described in the specification in such a way as to enable one skilled in the art to make and/or use the presently disclosed subject matter.

Claims 1, 2 and 6 have been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the claims fail to comply with the written description requirement.

Claims 1 and 6 presently stand rejected under the provisions of 35 U.S.C. § 102(b) as allegedly being anticipated by PCT International Patent Application Publication No. WO 01/57190 to Tang et al. (hereinafter referred to as "Tang et al.").

Claims 1 and 2 presently stand rejected under the provisions of U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,943,241 to Isogia et al. (hereinafter referred to as "Isogia et al.").

Claim 1 has been amended to more particularly recite the presently disclosed subject matter. Support for the amendment can be found throughout the specification as filed, including particularly in original claims 2 and 6; at page 3, lines 4-15; and in Figure 14. No new matter has been added.

New claim 13 has been added herein. Support for new claim 13 can be found throughout the specification as originally filed, including particularly in original claims 1 and 6. No new matter has been added.

Reconsideration of the application based on the arguments set forth herein is respectfully requested.

II. Response to the 35 U.S.C. §112, First Paragraph, Enablement Rejection of Claims 1, 2 and 6

Claims 1, 2 and 6 presently stand rejected under the enablement requirement of 35 U.S.C. §112, first paragraph. The Patent Office asserts that the claims contain subject matter not described in the specification in such a way as to enable one skilled in the art to make and/or use the presently disclosed subject matter. Particularly, the Patent Office contends that no working examples are provided that demonstrate the ability of any ZHX3 protein to treat hepatoma or to alter the expression of pyruvate kinase M gene type II hexokinase gene in any model.

After careful consideration of the rejection and the Patent Office's basis therefore, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants respectfully submit that claims 2 and 6 have been canceled without prejudice. As such, the instant rejection with respect to these claims is believed to be rendered moot.

Without acquiescing to the contentions of the Patent Office, applicants respectfully submit that claim 1 has been amended to recite, *inter alia*, "A drug agent...comprising a protein as an effective component having an amino acid sequence of SEQ ID NO: 1, wherein the protein comprises amino acids 242-502 of SEQ ID NO: 1 and has at least 85% sequence identity to SEQ ID NO: 1, wherein the gene is a type II hexokinase or a pyruvate kinase M gene." Support for the amendment to claim 1 can be found throughout the specification as originally filed, and particularly in original claims 2 and 6; at page 3, lines 4-15; and in Figure 14. No new matter has been added.

Applicants respectfully submit that present claim 1 is believed to be adequately enabled. Applicants respectfully submit that the specification describes a drug agent comprising a protein that is a transcriptional repressor of a pyruvate

kinase M (PKM) and type II hexokinase (HKII) gene expressed in hepatoma cells as an effective component comprising an amino acid sequence of SEQ ID NO: 1 or comprising amino acids 242-502 of SEQ ID NO: 1 and having at least 85% sequence identity to SEQ ID NO: 1, as presently claimed. Furthermore, applicants respectfully submit that the previously submitted 37 C.F.R. § 1.132 Declaration, that includes experimental data describing ZHX3 transcriptional repression of PKM and HKII, provides further support for the enabling nature of the instant specification, particularly with regard to present claim 1. Finally, the Patent Office, at page 12 of the instant Final Official Action, admits that amino acids 303-502 of SEQ ID NO: 1 function as a transcriptional repression domain that regulates the expression of PKM and HKII in hepatoma cells. Accordingly, applicants respectfully submit that one of ordinary skill in the art, upon review of the presently disclosed and claimed subject matter, would be adequately enabled to make and/or use the subject matter of present claim 1.

Thus, present claim 1 is believed to be in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph. Applicants respectfully request withdrawal of the instant rejection of claim 1 under 35 U.S.C. § 112, first paragraph. A Notice of Allowance is also respectfully requested.

III. Response to the 35 U.S.C. §112, First Paragraph, Written Description

Rejection of Claims 1, 2 and 6

Claims 1, 2 and 6 have been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the claims fail to comply with the written description requirement. Particularly, the Patent Office contends that given the genus of proteins encompassed by the rejected claims, and given the limited description provided by the prior art and specification with regard to structures necessary to regulate the expression of type II hexokinase and pyruvate kinase M to treat hepatoma, the skilled artisan would not have been able to envision a sufficient number of specific

embodiments that meet the functional limitations of the claims. Thus, the Patent Office contends that there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision those proteins that satisfy the functional limitations of the claims. Therefore, the Patent Office asserts that a skilled artisan would have reasonably concluded applicants were not in possession of the claimed invention for claims 1, 2 and 6.

After careful consideration of the rejection and the Patent Office's basis therefore, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants respectfully submit that claims 2 and 6 have been canceled without prejudice. As such, the instant rejection with respect to these claims is believed to be rendered moot.

Without acquiescing to the contentions of the Patent Office, applicants respectfully submit that claim 1 has been amended to recite, *inter alia*, "A drug agent...comprising a protein as an effective component having an amino acid sequence of SEQ ID NO: 1, wherein the protein comprises amino acids 242-502 of SEQ ID NO: 1 and has at least 85% sequence identity to SEQ ID NO: 1, wherein the gene is a type II hexokinase or a pyruvate kinase M gene." Support for the amendment to claim 1 can be found throughout the specification as originally filed, and particularly in original claims 2 and 6; at page 3, lines 4-15; and in Figure 14. No new matter has been added.

Applicants respectfully submit that present claim 1 is believed to be adequately supported by the specification. Applicants convey to the skilled artisan that they were in possession of a drug agent comprising a protein as an effective component that is a transcriptional repressor of a gene expressed specifically in hepatoma cells. In particular, applicants describe a drug agent comprising a protein that is a transcriptional repressor of a PKM or HKII gene expressed in hepatoma cells as an effective component comprising an amino acid sequence of SEQ ID NO: 1 or

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comprising amino acids 242-502 of SEQ ID NO: 1 and having at least 85% sequence identity to SEQ ID NO: 1, as presently claimed. Further, amino acids 242-502 of SEQ ID NO:1 includes the dimerization domain and interaction domain in addition to the repression domain (see Figure 14 of the specification).

Accordingly, the instant specification allows a person of ordinary skill in the art to recognize the drug agents that are being claimed, and recognition of what is being claimed suffices for compliance with the written description requirement. Therefore, applicants respectfully assert that present claim 1 is adequately supported by the instant application.

Thus, present claim 1 is believed to be in compliance with the written description requirement of 35 U.S.C. § 112, first paragraph. Applicants respectfully request withdrawal of the instant rejection of claim 1 under 35 U.S.C. § 112, first paragraph. A Notice of Allowance is also respectfully requested.

IV. Response to the 35 U.S.C. § 102(b) Rejection of Claims 1 and 6
Based on Tang et al.

Claims 1 and 6 presently stand rejected under the provisions of 35 U.S.C. § 102(b) as allegedly being anticipated by PCT International Patent Application Publication No. WO 01/57190 to Tang et al. (hereinafter referred to as "Tang et al."). The Patent Office asserts that Tang et al. teaches each and every element of the rejected claims such that the claims are anticipated.

After careful consideration of the rejection and the Patent Office's basis therefore, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants respectfully submit that claim 6 has been canceled without prejudice. As such, the instant rejection with respect to this claim is believed to be rendered moot.

As discussed hereinabove, claim 1 has been amended to recite, *inter alia*, “wherein the protein comprises amino acids 242-502 of SEQ ID NO: 1” Support for the amendment to claim 1 can be found throughout the specification as originally filed, and particularly in original claims 2 and 6; at page 3, lines 4-15; and in Figure 14. No new matter has been added.

Applicants respectfully submit that Tang *et al.* does not teach or suggest each and every element of present claim 1, including but not necessarily limited to amino acids 242-502 of SEQ ID NO: 1. Accordingly, applicants respectfully submit that Tang *et al.* does not support a rejection of claim 1 under 35 U.S.C. § 102(b). Thus, withdrawal of the instant rejection of claim 1 under 35 U.S.C. § 102(b) is respectfully requested. A Notice of Allowance is also respectfully requested.

V. Response to the 35 U.S.C. § 102(e) Rejection of Claims 1 and 2

Based on Isogia *et al.*

Claims 1 and 2 presently stand rejected under the provisions of U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,943,241 to Isogia *et al.* (hereinafter referred to as “Isogia *et al.*”). Particularly, the Patent Office asserts that Isogia *et al.* teaches each and every element of the rejected claims such that the claims are anticipated.

After careful consideration of the rejection and the Patent Office’s basis therefore, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants respectfully submit that claim 2 has been canceled without prejudice. As such, the instant rejection with respect to this claim is believed to be rendered moot.

As discussed hereinabove, claim 1 has been amended to recite, *inter alia*, “wherein the protein comprises amino acids 242-502 of SEQ ID NO: 1 and has at least 85% sequence identity to SEQ ID NO: 1”. Support for the amendment to claim

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1 can be found throughout the specification as originally filed, and particularly in original claims 2 and 6; at page 3, lines 4-15; and in Figure 14. No new matter has been added.

The Patent Office contends that SEQ ID NO: 2005 of Isogai et al. is 100% identical to amino acids 300-956 of the presently claimed SEQ ID NO: 1. However, even assuming *arguendo* that this assertion is correct, Isogai et al. fails to teach a protein comprising amino acids 242-502 of SEQ ID NO: 1, or a protein having at least 85% sequence identity to SEQ ID NO: 1. It is believed that a protein having at least 85% sequence identity to SEQ ID NO: 1 would necessarily have a greater number of amino acids of SEQ ID NO: 1 than the fragment disclosed by Isogai et al.

Accordingly, applicants respectfully submit that Isogai et al. fails to teach or suggest each and every element of present claim 1. Therefore, applicants respectfully submit that Isogai et al. does not support a rejection of claim 1 under 35 U.S.C. § 102(e). Thus, withdrawal of the instant rejection of claim 1 under 35 U.S.C. § 102(e) is respectfully requested. A Notice of Allowance is also respectfully requested.

DISCUSSION OF NEW CLAIM

New claim 13 has been added herein. Support for new claim 13 can be found throughout the specification as originally filed, including particularly in original claims 1 and 6. No new matter has been added.

Applicants respectfully submit that new claim 13 is patentable over the references cited by the Patent Office for at least the reasons set forth herein above with respect to independent claim 1. Applicants further respectfully submit that new claim 13 is allowable over the cited art of record. Additionally, applicants respectfully submit that new claim 13 is patentable for at least the reasons discussed hereinabove. Accordingly, allowance of new claim 13 is respectfully requested.

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CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

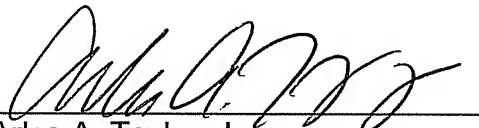
DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any additional fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

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